Application No: 10/630,376 Docket No. 03-009

REMARKS

Rejection under 35 U.S.C. § 102(b)

Claim 41 is rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,555,618 to Winkler (hereinafter referred to as "Winkler").

Independent claim 41 recites:

> a solid matrix of fused insulative material surrounding and electrically insulating each of the first and second plurality of conductors thereby forming a lead body, wherein the solid matrix of materials (i) retains each of the first plurality of conductors at the substantially same first radial depth in the lead body, (ii) retains the second plurality of conductors at the substantially same second radial depth in the lead body, the second radial depth being underneath the first radial depth, and (iii) retains each conductor of the first and second plurality of conductors at a prescribed distance from adjacent conductors, wherein the solid matrix of fused insulative material does not possess an inter-layer boundary between the first and second radial depths.

When examining the claims, the Examiner has stated that the Examiner was unsure of the meaning of the element "the insulative material does not possess an inter-layer boundary." The Examiner stated that this element was interpreted to refer to the fusing of the material between the first and second radial depths. *See* Office Action, page 3. Applicant notes that the Examiner's interpretation is correct, i.e., the insulative material is fused along the lead body.

The Office Action also asserts that because different materials can be used during fabrication of a lead as disclosed in the present application, a "somewhat" of a boundary can be formed between the first and second radial depths. Office Action, page 3. Applicant respectfully traverses this assertion. The claim language does not merely refer to any type of a boundary. Instead, the claim language refers to an "inter-layer" boundary. The claimed subject matter does not possess an "inter-layer" boundary, because there are no interposing layers between the first and second radial depths. Instead, the insulative material between the first and second radial depths are in the form of a fused matrix.

In the rejection under 35 U.S.C. § 102(b), the Office Action states that the lead manufacturing process of Winkler for the embodiment shown in Fig. 10 would inherently "tend to fuse the two layers of polyurethane together." Office Action, page 3. Specifically,

the Office Action states that the embedding of the wires requires heating and the heating would necessarily fuse various layers because the layers are of a shore D hardness of 75. Office Action, page 3.

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *See* MPEP § 2112 citing *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Applicant respectfully submits that the disclosure of Winkler does not satisfy the inherency requirements to establish that the various layers (layers 44a and 44b) of the embodiment of Fig. 10 would be fused together. Winker discloses a process where a first layer of plastic is extruded. The polymer layer can be heated using "hot air guns" while conductors are embedded in the polymer layer under "simple hand tension." *See* col. 6, lines 17-23. Winkler also discloses forming another layer of plastic by over-extruding the prior plastic layer and wires. Another set of wires are then embedded in the topmost layer of plastic.

In regard to the heating details upon which the inherency argument relies, Winkler states that only a sufficient amount of heat is provided by the hot air guns to "temporarily decrease the harness of the hard plastic to allow the wire 45 to become embedded therein under simple hand tension." However, the mere fact that heat is provided to temporarily decrease the hardness of the plastic for wire winding purposes does not mean that sufficient heat is necessarily provided to fuse the two interposing layers such that there is no "inter-layer boundary between the first and second radial depths." And even assuming that some fusing occurs between the two layers (which Applicant does not concede), there is no basis to conclude that the fusing occurs uniformly along the two layers such that there is no "inter-layer boundary."

Importantly, the explicit disclosure of Winkler is inconsistent with the position that the heating necessarily fuses the two layers such that there is no "inter-layer boundary" in the completed catheter. Winkler explicitly teaches that the purpose of the plastic layer into which the wires are embedded is to "preclude accidental movement of the spaced apart

plurality of wound wires," col. 5, lines 60-61, i.e., to "immobilize" the wires during further catheter processing, col. 6, lines 23-26. If sufficient heat were applied so that the topmost layer and the next underlying layer were placed in a molten state to fuse the layers without an "interlayer boundary," the molten material would be free to flow. The flow of the molten plastic would defeat the purpose of "immobilizing" the wires. That is, the wires would be free to move due to variable forces in the hand-winding process, because the molten plastic would not hold the wires in place. Also, there would be nothing to keep the second set of wires from penetrating through the molten plastic to contact the first set of wires.

Additionally, Applicant notes that it is highly relevant that the description of Winkler describes the catheter is terms of discrete layers and shown the cross-section of the catheter as comprising discrete layers.

Accordingly, Winkler does not disclose that layers 44a and 44b do not "possess an inter-layer boundary between the first and second radial depths" as required claim 41 either explicitly or by inherency.

Therefore, Winkler does not anticipate claim 41.

Rejection under 35 U.S.C. § 103(a)

Claims 41-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Winkler (alone) or in the alternative in view of U.S. Patent No. 5,334,169 to Brown (hereinafter referred to as "Brown").

Claims 51-60 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Winkler (alone or in the alternative in view of Brown) in view of U.S. Patent No. 5,733,322 to Starkebaum (hereinafter referred to as "Starkebaum").

Independent claims 41 and 51 recite:

> a solid matrix of fused insulative material surrounding and electrically insulating each of the first and second plurality of conductors thereby forming a lead body, wherein the solid matrix of materials (i) retains each of the first plurality of conductors at the substantially same first radial depth in the lead body, (ii) retains the second plurality of conductors at the substantially same second radial depth in the lead body, the second radial depth being underneath the first radial depth, and (iii)

retains each conductor of the first and second plurality of conductors at a prescribed distance from adjacent conductors, wherein the solid matrix of fused insulative material does not possess an inter-layer boundary between the first and second radial depths.

For the reasons discussed above in regard to the rejection under 35 U.S.C. § 102(b), Winkler does not teach or suggest the limitations of claims 41 and 51.

The Office Action takes a secondary position that if Winkler does not teach or suggest a fused insulative material that "does not possess an inter-layer boundary between the first and second radial depths," it would have been obvious in view of Brown.

Applicant respectfully submits that the catheter in Brown is adapted for a very different purpose than the subject matter of Winkler (and also the claimed subject matter). Because of the difference, one of ordinary skill in the art would not be motivated to utilize the co-extrusion and concurrent delivery of "reinforcement strands" of Brown for the Winkler stimulation lead.

Brown is directed to a reinforced catheter with thin monolithic walls having "reinforcing strands" spirally wound therein. *See* Abstract of Brown. The purpose of the "reinforcing strands" is to provide "circumferentially inflexibility" to allow the catheter to be "steered" through the vascular system of a patient. *See* col. 6, lines 7-16 and lines 26-30 and col. 1, lines 36-42. The reinforcing strands are integrated within the catheter walls by coextruding "from inside and outside of the strands while the material for the wall 9 is molten and fusible with the strands included in it." Col. 6, lines 30-34.

However, the "reinforcing strands" of Brown cannot be read upon the recited first or second plurality of conductors. Specifically, as seen in claims 41 and 51, each conductor of the first and second plurality of conductors are "individually electrically isolated" and are coupled to a respective electrode. Additionally, the conductors in claims 41 and 51 are maintained at prescribed distances from each other and the radial depth of the conductors are controlled. The purpose of such positional control is to maintain the electrical isolation and to facilitate electrode formation. As is known in the art, electrode formation frequently occurs by ablating (e.g., using a pulsed laser) insulative material in the lead body to expose a conductor. If the positions of the conductors are not controlled, the ablation can expose two

conductors at once (e.g., when the two conductors are too close) or can create an opening through to the lumen of the lead body (e.g., when the radial depth of a conductor is too close to the lumen). In either case, the lead body becomes unsuitable for use as a stimulation lead. Additionally, Applicant respectfully refers the Examiner to Fig.s 4A-4D of Winkler as an example of electrode formation.

The "reinforcing strands" of Brown are not disclosed as being coupled to electrodes. Additionally, one of ordinary skill in the art would not be motivated to use the reinforcing strands or the associated fabrication process for conductors coupled to electrodes in a stimulation lead. Specifically, there is no disclosed mechanism in Brown for controlling the positioning of the reinforcement strands during the co-extrusion process (other than wrapper 22 in Fig. 6). Because the reinforcement strands are merely contained in molten plastic material, the reinforcement strands are subject to dislocation by relatively small forces. Accordingly, the disclosed co-extrusion process of Brown would not be viewed as appropriate by one of ordinary skill in the art for stimulation leads as evidenced by Winkler's statement of the importance of precluding "accidental movement of the spaced apart plurality of wound wires." *See* col. 5, lines 60-61 of Winkler.

Starkebaum is merely cited in the Office Action to demonstrate that it is known to use stimulation leads with pulse generators. Starkebaum does not teach or suggest the recited characteristics of the fused insulative material, conductors, and electrodes of claims 41 and 51.

Thus, from the teachings and suggestions of the applied references (either alone or in combination), one of ordinary skill in the art would not have been motivated to arrive at the claimed subject matter of claims 41 and 51. A prima facie case of obviousness has not been established for these claims. Claims 42-50 and 52-60 respectively depend from claims 41 and 51 and a prima facie case of obviousness has not been established for these claims.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. Applicant believes no fee is due with this response.

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Respectfully submitted,

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